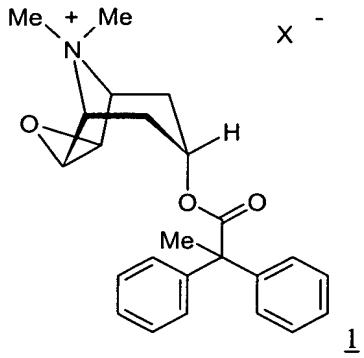
Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

1. (currently amended) A ~~P~~pharmaceutical compositions~~, characterised in that they contain~~ comprising:

(a) ~~-~~ one or more anticholinergics of formula 1



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wherein:

X^- ~~denotes~~ is an anion with a single negative charge~~, preferably an anion selected from the group consisting of chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate,~~; and

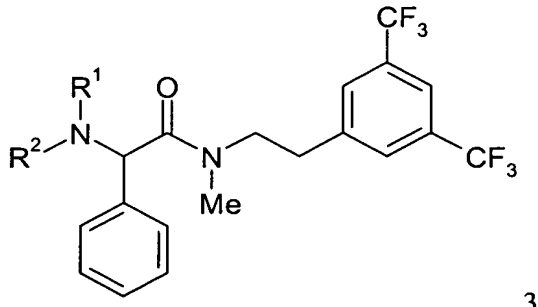
(b) ~~combined with~~ one or more NK_1 receptor antagonists ~~(2)~~,

~~optionally in the form of~~or ~~the~~an enantiomers, mixtures of ~~the~~ enantiomers, ~~or in the form of the~~ racemates ~~thereof~~, ~~optionally in the form of the~~ solvates, or hydrates thereof ~~and optionally together with a pharmaceutically acceptable excipient~~.

2. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, wherein ~~characterised in that in the compounds of formula 1~~ X^- is ~~a negatively charged anion selected from the group consisting of~~ chloride, bromide, iodide, sulphate, phosphate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate, 4-toluenesulphonate, ~~and~~or methanesulphonate.

3. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that in the compounds of formula 1~~wherein X^- ~~denotes~~is bromide.

4. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, wherein~~characterised in that 2~~ the NK_1 receptor antagonists ~~is~~are selected from ~~among~~ BIIF 1149, CP-122721, FK-888, ~~NKP 608C,~~ NKP 608A, CGP 60829, SR 48968 (Saredutant), SR 140333 (Nolpitantium besilate/chloride), LY 303—870 (Lanepitant), MEN-11420 (Nepadutant), SB 223412, MDL-105172A, MDL-103896, MEN-11149, MEN-11467, DNK 333A, SR-144190, YM-49244, YM-44778, ZM-274773, MEN-10930, S-19752, Neuronorm, ~~YM-35375,~~ DA-5018, MK-869, L-754030, CJ-11974, L-758298, DNK-33A~~, 6b-I~~, CJ-11974, TAK-637, GR 205171, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[(3-hydroxy-propyl)-methyl-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(2-hydroxy-1-hydroxymethyl-ethylamino)-piperidin-1-yl]-N-methyl-2-phenylacetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(cyclopropylmethyl-methyl-amino)-piperidin-1-yl]-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[(2-hydroxy-ethyl)-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[cyclopropylmethyl-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, ~~and the~~or an arylglycinamide compound~~derivatives~~ of ~~general~~ formula 3



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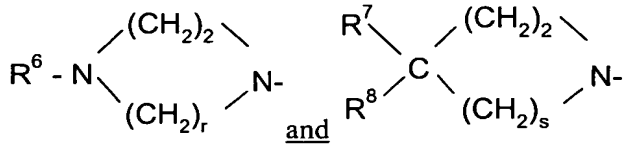
wherein:

R^1 and R^2 together with the N to which they are bound form a ring of formula



and

wherein r and s are each 2 or 3,;

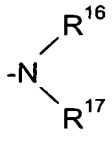
R^6- ~~denotes~~is H, -C_1-C_5-alkyl, C_3-C_5-alkenyl, propynyl, hydroxy(C_2-C_4)alkyl, methoxy(C_2-C_4)alkyl, di(C_1-C_3)alkylamino(C_2-C_4)alkyl, amino(C_2-C_4)alkyl, amino, di(C_1-C_3)alkylamino, monofluoro- to perfluoro(C_1-C_2)alkyl, N-methylpiperidinyl, pyridyl, pyrimidinyl, pyrazinyl, or pyridazinyl,

R^7 ~~has~~ is one of ~~the meanings~~ (a) to (~~d~~c),

(a) hydroxy,

(b) 4-piperidinopiperidyl,

(c)



wherein R^{16} and R^{17} are each independently ~~of each other denote~~ H, (C_1-C_4)alkyl, (C_3-C_6)cycloalkyl, hydroxy(C_2-C_4)alkyl, dihydroxy(C_2-C_4)alkyl, (C_1-C_3)alkoxy(C_2-C_4)alkyl, phenyl(C_1-C_4)alkyl, or di(C_1-C_3)alkylamino(C_2-C_4)alkyl, and

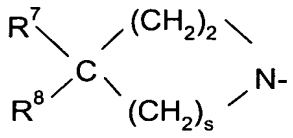
R^8 ~~denotes~~ is H,

~~optionally in the form of the~~or an enantiomers, ~~and~~ mixtures of enantiomers ~~thereof~~, ~~optionally in the form of the~~or racemates thereof.

5. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that~~ wherein ~~2~~ NK_1 receptor antagonists ~~is~~are selected from the group consisting of BIIF 1149, CP-122721, CGP 60829, MK-869,- CJ-11974, GR 205171, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[(3-hydroxy-propyl)-methyl-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(2-hydroxy-1-hydroxymethyl-ethylamino)-piperidin-1-yl]-N-methyl-2-phenylacetamide, N-[2-

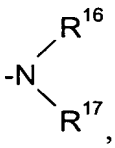
(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(cyclopropylmethyl-methyl-amino)-piperidin-1-yl]-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[(2-hydroxy-ethyl)-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-{4-[cyclopropylmethyl-(3-hydroxy-propyl)-amino]-piperidin-1-yl}-N-methyl-2-phenyl-acetamide, ~~and the~~or an arylglycinamide compound~~derivatives~~ of ~~general~~ formula 3, wherein:

R^1 and R^2 together with the N to which they are bound form a ring of formula



wherein s is 2 or 3~~,~~;

R^7 ~~denotes a group~~is



wherein R^{16} and R^{17} are independently ~~of each other denote~~ H, $(C_1\text{-}C_4)$alkyl, $(C_3\text{-}C_6)$cycloalkyl, hydroxy$(C_2\text{-}C_4)$alkyl, dihydroxy$(C_2\text{-}C_4)$alkyl, $(C_1\text{-}C_3)$alkoxy$(C_2\text{-}C_4)$alkyl, phenyl$(C_1\text{-}C_4)$alkyl, or di$(C_1\text{-}C_3)$alkylamino$(C_2\text{-}C_4)$alkyl, and

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R^8 ~~denotes~~ is H,

~~optionally in the form of the~~or an enantiomers~~, and~~ mixtures of enantiomers~~, thereof and optionally in the form of the~~or racemates thereof.

6. (currently amended) The ~~P~~pharmaceutical compositions according to ~~one of~~ claim 1, ~~wherein characterised in that 2~~ the NK_1 receptor antagonist is (S)-N-[2-(3,5-bis-trifluoromethyl-phenyl)-ethyl]-2-[4-(2-hydroxy-1-hydroxymethyl-ethylamino)-piperidin-1-yl]-N-methyl-2-phenylacetamide or an acid addition salt thereof.

7. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that~~wherein the weight ratios of ~~1~~ the anticholinergic to ~~2~~ NK_1 receptor antagonist ~~are~~is in the range from 1:100 to 100:1~~, preferably from 1:80 to 80:1~~.

8. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that~~wherein a single administration corresponds to a dosage of the combination of ~~active substances 1~~the anticholinergic and ~~2~~ the NK_1 receptor antagonist of 0.01 µg to 10,000 µg~~, preferably from 0.1 to 2,000µg~~.

9. (currently amended) The ~~P~~pharmaceutical composition according to claim 1, ~~characterised in that~~wherein ~~it~~the pharmaceutical composition is in the form of a formulation suitable for inhalation.

10. (currently amended) The ~~P~~pharmaceutical composition according to claim 9, wherein~~characterised in that it~~ the pharmaceutical composition is a formulation selected from ~~among~~ inhalable powders, propellant-containing metering aerosols, and propellant-free inhalable solutions or suspensions.

11. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, ~~characterised in that it~~wherein the pharmaceutical composition is an inhalable powder which contains ~~1~~the anticholinergic and ~~2~~ the NK_1 receptor antagonist in admixture with suitable physiologically acceptable excipients selected from ~~among~~ the monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, salts, or mixtures of these excipients.

12. (currently amended) The ~~I~~inhalable powder according to claim 11, ~~characterised in that~~wherein the excipient has a maximum average particle size of up to 250 µm~~, preferably between 10 and 150µm~~.

13. (currently amended) A ~~C~~capsule~~, characterised in that it~~ containsing an inhalable powder according to claim 11 or 12.

14. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, wherein the pharmaceutical composition~~characterised in that it~~ is an inhalable powder consisting essentially of the NK_1 receptor antagonist~~which contains only active substances 1 and 2 as its ingredients~~.

15. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, wherein the pharmaceutical composition~~characterised in that it~~ is a propellant-containing inhalable aerosol comprising the anticholinergic~~which contains 1~~ and ~~2~~ the NK_1 receptor antagonist in dissolved or dispersed form.

16. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 15, ~~characterised in that it contains, as~~wherein the propellant gas is~~, hydrocarbons such as~~ n-propane, n-butane, or isobutane, or ~~halohydrocarbons such as~~ chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane, or cyclobutane.

17. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 16, ~~characterised in that~~wherein the propellant gas is TG11, TG12, TG134a, TG227, or a mixtures thereof.

18. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 15, ~~characterised in that it optionally contains~~further comprising one or more other ingredients selected from the group consisting of cosolvents, stabilizers, surfactants, antioxidants, lubricants, and means for adjusting the pH.

19. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 15, ~~characterised in that it may~~wherein the inhalable aerosol contains up to 5 wt.-% of the anticholinergic ~~active substance 1~~ and/or 2the NK_1 receptor antagonist.

20. (currently amended) The ~~P~~pharmaceutical composition according to claim 10, ~~characterised in that it~~wherein the pharmaceutical composition is a propellant-free inhalable solution or suspension which contains water, ethanol, or a mixture of water and ethanol as solvent.

21. (currently amended) The ~~I~~inhalable solution or suspension according to claim 20, ~~characterised in that~~wherein the pH range is 2 ~~-~~to 7~~, preferably 2 - 5~~.

22. (currently amended) The ~~I~~inhalable solution or suspension according to claim 21, wherein~~characterised in that~~ the pH is adjusted by means of an acid selected from among hydrochloric acid, hydrobromic acid, nitric acid, sulphuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid, and propionic acid, or a mixtures thereof.

23. (currently amended) The ~~I~~inhalable solution or suspension according to claim 20, ~~characterised in that it optionally contains~~further comprising other co-solvents and/or excipients.

24. (currently amended) The ~~I~~inhalable solution or suspension according to claim 23, ~~characterised in that it contains as~~wherein the co-solvents ~~ingredients which contain hydroxyl groups or other polar groups, e.g.~~are ~~alcohols - particularly~~ isopropyl alcohol, ~~glycols - particularly~~ propyleneglycol, polyethyleneglycol, polypropyleneglycol, glycolether, glycerol, polyoxyethylene alcohols, ~~and~~or polyoxyethylene fatty acid esters.

25. (currently amended) The i~~I~~nhalable solution or suspension according to claim 23, ~~characterised in that it contains as~~ wherein the excipients are surfactants, stabilis~~z~~ers, complexing agents, antioxidants and/or preservatives, flavo~~u~~rings, pharmacologically acceptable salts, ~~and/~~or vitamins.

26. (currently amended) The ~~I~~inhalable solution or suspension according to claim 25, ~~characterised in that it contains as~~wherein the complexing agent is edi~~e~~tic acid or a salt of edi~~e~~tic acid, preferably sodium edetate.

27. (currently amended) The ~~I~~inhalable solution or suspension according to claim 25, ~~characterised in that it contains, as~~wherein the antioxidants~~, compounds selected from among~~ are ascorbic acid, vitamin A, vitamin E, ~~and~~or tocopherols.

28. (currently amended) The ~~I~~inhalable solution or suspension according to claim 25, ~~characterised in that it contains as~~wherein the preservatives ~~compounds selected from~~are cetyl pyridinium chloride, benzalkonium chloride, benzoic acid, ~~and~~or benzoates.

29. (currently amended) The ~~I~~inhalable solution or suspension according to claim 23, consisting essentially of ~~characterised in that it contains, in addition to the active substances 1 and 2~~the anticholinergic, the NK_1 receptor antagonist, ~~and~~ the solvent, ~~only~~ benzalkonium chloride, and sodium edetate.

30. (currently amended) The ~~I~~inhalable solution or suspension according to claim 23, ~~characterised in that it contains, in addition to the active substances~~consisting essentially of ~~1~~ the anticholinergic, ~~and 2~~the NK_1 receptor antagonist, ~~and~~ the solvent, ~~only~~and benzalkonium chloride.

31. (currently amended) The ~~I~~inhalable solution or suspension according to claim 20, ~~characterised in that it~~wherein the inhalable solution or suspension is a concentrate or a sterile ready-to-use inhalable solution or suspension.

32. (currently amended) A method of nebulis~~z~~ing the inhalable solution or suspension according to claim 20, ~~in~~wherein the inhalable solution or suspension is nebulized using an inhaler according to WO 91/14468 or an inhaler as described in Figures 6a and 6b of WO 97/12687 ~~comprising providing an inhalable solution according to claim 20~~.

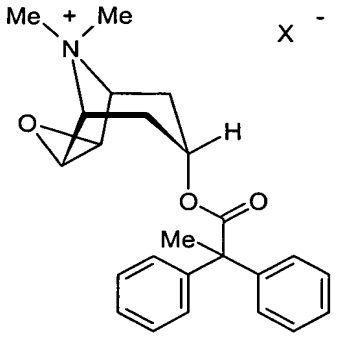
33. (currently amended) The method of nebulizing an inhalable solution or suspension according to ~~to~~ claim 31, ~~for nebulising in~~wherein the inhalable solution or suspension is nebulized using an energy-operated free-standing or portable nebulis<u>z</u>er which produces inhalable aerosols by means of ultrasound or compressed air ~~according to the Venturi principle or other principles~~.

34. (currently amended) The ~~P~~propellant-containing inhalable aerosol according to claim 17, ~~characterised in that~~wherein the propellant gas is TG134a, TG227, or a mixture thereof.

35. (currently amended) A ~~M~~method of treatment and/or prevention of an inflammatory or obstructive diseases of the respiratory tract comprising administering to a mammal in need of such ~~a~~ treatment a therapeutically effective amount of a pharmaceutical composition according to claim 1.

36. (currently amended) A kit comprising:

(a) a first container containing a first pharmaceutical formulation comprising one or more anticholinergics of formula 1



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wherein:

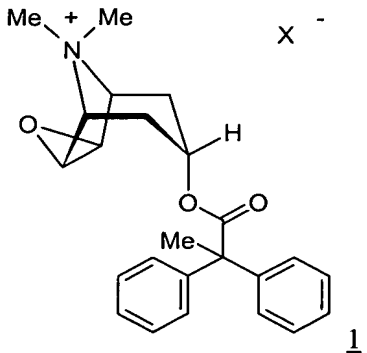
X$^-$ ~~denotes~~is an anion with a single negative charge~~, preferably an anion selected from the group consisting of chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate~~,

~~optionally in the form of the~~or an enantiomers, mixtures of the enantiomers, ~~or in the form of the~~ racemates ~~thereof~~, ~~optionally in the form of the~~ solvates, or hydrates ~~and optionally together with a pharmaceutically acceptable excipient~~ thereof; and

(b) a second container containing a second pharmaceutical formulation comprising ~~a~~ one or more NK_1 receptor antagonists ~~(2)~~, ~~optionally in the form of the~~or an enantiomers, mixtures of the enantiomers, ~~or in the form of the~~ racemates ~~thereof~~, ~~optionally in the form of the~~ solvates, or hydrates thereof;

~~each container each optionally further containing a pharmaceutically acceptable excipient~~.

37. (currently amended) A ~~M~~method of treatment and/or prevention of an inflammatory or obstructive diseases of the respiratory tract comprising administering simultaneously or sequentially to a mammal in need of such a treatment a therapeutically effective amount of ~~the~~a first– pharmaceutical formulation ~~(1)~~ comprising –one or more anticholinergics of formula 1



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wherein:

X^- ~~denotes~~is an anion with a single negative charge~~, preferably an anion selected from the group consisting of chloride, bromide, iodide, sulphate, phosphate, methanesulphonate, nitrate, maleate, acetate, citrate, fumarate, tartrate, oxalate, succinate, benzoate and p-toluenesulphonate~~,

and a second pharmaceutical formulation comprising one or more NK_1 receptor antagonists ~~(2)~~,

each ~~of (1)~~the anticholinergic and ~~(2)~~ the NK_1 receptor antagonist optionally in the form of an~~the~~ enantiomers, mixtures of ~~the enantiomer~~enantiomers,s ~~or in the form of the~~ racemates

~~thereof~~, ~~optionally in the form of the~~ solvates, or hydrates thereof ~~and optionally together with a pharmaceutically acceptable excipient;~~

~~wherein the first and second pharmaceutical formulations are administered simultaneously or separately~~.